

Hearing on Proposed Regulation: Green Chemistry Hazard Traits

(Proposed Article for Title 4.5, Division 22,
California Code of Regulations)

January 31, 2011

Office of Environmental Health Hazard Assessment
Cal/EPA Headquarters



Topics

- SB 509 mandate
- Development of Proposed Regulation
- Hazard Trait framework
- Regulation overview
- Initial Statement of Reasons
- Next steps



Legislative Mandate

(Health and Safety Code 25256.1; 2008 Senate Bill 509)

“On or before January 1, 2011,
the [OEHHA] shall evaluate and specify
the **hazard traits and environmental and
toxicological end-points and any other relevant
data that are to be included in the clearinghouse.**
The office shall conduct this evaluation
in consultation with the department
and all other appropriate state agencies,
after one or more public workshops,
and an opportunity for all interested parties to
comment.”

Development of Proposed Regulation

- Four public workshops
 - January 29, 2009
 - March 15-16, 2010
 - May 10-11, 2010
 - August 23, 2010
- Green Ribbon Science Panel consultations
- California department and agency consultations
- Industry and NGO scientist meetings on methods for screening of hazards

Development of Proposed Regulation

- Released pre-regulatory draft in August 2010 for 45-day review
- Received comments from industry, NGOs and academics
- Revised draft per comments
- December 17, 2010 - Released Proposed Regulation for 60-day public review

Differences from Pre-regulatory Draft

- Removed section on “Sources and Methodologies”
 - proposed regulation establishes information to include in Clearinghouse
 - proposed regulation describes strong and suggestive evidence for use in weighing evidence
- Added hazard traits:
 - impairment of waste management organisms
 - domestic animal toxicity
- Removed or condensed some hazard traits
- Clarified definitions and wording in some traits

Proposed Regulation's Hazard Trait Framework

- General types of hazard traits
 - Toxicological
 - Environmental
 - Exposure Potential
 - Physical
- Specific hazard traits, for each general type
- For each specific hazard trait:
 - Endpoints – observed adverse effects (manifestation of the hazard trait)
 - Other relevant data – non-endpoint data that indicate a substance may have a hazard trait

Overview of Proposed Regulation

- General – Purpose, Framework, Definitions
- Specific Hazard Traits, Endpoints and Other Relevant Data

Toxicological

Environmental

Exposure Potential

Physical

Toxicological Hazard Traits

- Carcinogenicity
- Cardiovascular Toxicity
- Dermatotoxicity
- Developmental Toxicity
- Endocrine Toxicity
- Epigenetic Toxicity
- Genotoxicity
- Hematotoxicity
- Hepatotoxicity and Digestive System Toxicity
- Immunotoxicity
- Musculoskeletal Toxicity
- Nephrotoxicity and Other Urinary System Toxicity
- Neurotoxicity
- Ocular Toxicity
- Ototoxicity
- Reactivity in Biological Systems
- Reproductive Toxicity
- Respiratory Toxicity

Environmental Hazard Traits

- Domestic Animal Toxicity
- Eutrophication
- Impairment of Waste Management Organisms
- Loss of Genetic Diversity, including Biodiversity
- Phytotoxicity
- Wildlife Developmental Impairment
- Wildlife Growth Impairment
- Wildlife Reproductive Impairment
- Wildlife Survival Impairment

Evidence Descriptions for Toxicological and Environmental Hazard Traits

- To assist DTSC, the public and affected industries in understanding the strength of the evidence for a hazard trait
- Describes levels of available evidence indicating a substance has a hazard trait:
 - “Strong evidence”
 - “Suggestive evidence”

Exposure Potential Hazard Traits

- Ambient Ozone Formation
- Bioaccumulation
- Environmental Persistence
- Global Warming Potential
- Lactational or Transplacental Transfer
- Mobility in Environmental Media
- Particle Size or Fiber Dimension
- Stratospheric Ozone Depletion Potential

Physical Hazard Traits

- Explosivity
- Flammability
- Combustion Facilitation

Initial Statement of Reasons

- Required by law for any proposed regulation.
- Provides background information and explains the proposed regulation.
- Used to interpret the agency's intent in proposing the regulation
 - Enables the public to effectively comment on the proposed regulation during the adoption process.
- Provides detail on the scientific basis for the proposed regulation.
- Is being peer reviewed along with proposed regulatory language.

Next Steps

- Comment period ends February 15, 2011
- Peer review (as required by Health & Safety Code 57004)
- Review comments and revise regulation if appropriate
 - If revised, 15- or 45-day comment period, depending on the types of changes made.
 - If not revised, submit regulatory package to Office of Administrative Law
- Regulation effective after Office of Administrative Law approves


Written Comment on Proposed Regulation

By February 15

- Email to: fkammerer@oehha.ca.gov

OR

- Send to:
Fran Kammerer, Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812



PUBLIC COMMENTS

(during hearing
email comments to
coastalrm@calepa.ca.gov)